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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,857	01/30/2006	Melwyn Abreo	17243002001	2274

22511 7590 02/24/2009

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EXAMINER	
JARRELL, NOBLE E	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
02/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/566,857	ABREO ET AL.	
	Examiner	Art Unit	
	NOBLE JARRELL	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) *26-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18,24,25,53-58,61,70 and 71* is/are rejected.

7)☒ Claim(s) *17,19-23,59,60 and 62-69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/21/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The rejections under 35 U.S.C. 112 1st and 2nd paragraph have been overcome by the amendment filed 17 November 2008.

2. The rejection under 35 U.S.C. 103(a) regarding Fu et al. has been overcome by the amendment filed 17 November 2008.

3. The individual rejections under anticipatory and obvious-type double patenting have been overcome by the properly filed, and consequently approved, terminal disclaimers of 17 November 2008.

4. Claims 26-52 are withdrawn from consideration.

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 60/491080 and 60/491322, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. These provisional

applications fail to provide any support for the elected group. **Priority is granted to provisional application 60/491140, filed 29 July 2003.**

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-9, 12, 24, 55, and 70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* inhibition of stearoyl CoA desaturase (SCD), does not reasonably provide enablement for treatment or prevention of any disease or disorder linked to stearoyl CoA desaturase and for the simultaneous treatment and prevention of a disorder mediated by SCD. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to inhibition of stearoyl-CoA desaturase (SCD) and treatment and prevention of a disease mediated by SCD with compounds composed of an amide group attached to a pyridinyl ring, which is further attached to a piperazine ring. The piperazine ring is modified with a C(O)-(phenyl or naphthyl) group. Thus, the claims taken together with the specification imply that compounds of formula (I) can be used to inhibit SCD or any disease mediated by SCD.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Dobrzyn et al. (*Expert Opinion in Therapeutic Patents*, **2008**, *18(4)*, 457-60) teach that future research is needed to determine of SCD inhibition is useful (page 459, section 4).

Boss et al. (*Expert Opinion in Therapeutic Targets*, **2006**, *10(1)*, 119-134) teach that future research is needed to determine is SCD is a suitable target for treatment of obesity.

The simultaneous treatment and prevention of a disease is not possible. If a subject already has a disease, only alleviation is possible. If a subject does not have a disorder, only prevention is possible.

(5) The relative skill of those in the art:

Those of relative skill in the art are those with level of skill of the authors of the references cited to support the examiner's position. The relative skill of those in this art is MD's, PhD's, or those with advanced degrees and the requisite experience in treatment of a disorder mediated by SCD.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for *in vitro* inhibition of stearoyl CoA desaturase (example 5, pages 57-58 of the specification).

However, the specification does not provide guidance for alleviation or prevention of any disorder mediated by SCD. Treatment, as defined in the instant specification (page 27, lines 3-11), is defined as both prevention and alleviation of a disease.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to claims 1-9, 12, 24, 55, and 70 and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

8. Claims 2, 3, 12, 24, 55, and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are unclear because it is unclear what disease/disorder mediated by SCD is intended to be alleviated or prevented.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 57, 58, 61, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6677452, issued January 13, 2004, filed September 30, 1999).

Determining the scope and contents of the prior art

Chen et al. teach a compound of example 1 (columns 31-32) with a registry number of 334002-42-5. In this compound, instant variables R^1 and R^2 are H and R^3 is unsubstituted phenyl. Compositions of these compounds are taught from page 22, line 32 to page 23, line 17. These compounds are useful in the treatment of pain or infections (column 23, lines 5-6; column 25, lines 19-63), and are also useful as pesticides, acaricides, or antimicrobial (antibacterial) compounds (column 25, lines 19-63).

Ascertaining the differences between the prior art and the claims at issue

In the newly amended set of claims, instant group W-R^2 can be $C(O)NR^1R^2$. In this group, variable R^2 can be C_1C_{12}alkyl and variable R^1 can be H. Chen et al. teach a compound in which variables R^1 and R^2 are each H. In addition, the piperazine ring is attached to the 2-position of the pyridine ring, whereas in instant formula (I), the piperazine ring is attached to the 3-position of pyridine.

Resolving the level of ordinary skill in the pertinent art

One of ordinary skill realizes that the compound prepared by Chen et al. is a positional isomer and a homologue of instant formula (I).

Considering objective evidence present in the application indicating obviousness or nonobviousness

In re Norris (84 USPQ 458) teaches:

Counsel for appellant in their brief acknowledge that the record herein does not establish that the admittedly new and useful compound defined by the rejected claim possesses one or more specifically identified properties to be recognized as unobvious or unexpected, as measured by every conceivable standard. Since the product claimed herein admittedly possesses no unexpected characteristics or properties, in view of what has hereinbefore been said, it is not patentable.

Sterling Drug Inc. v. Watson, Comr. Pats. (108 USPQ 37) teaches:

The test to be applied in the matter of the patentability of a compound that is a homologue of another is whether the beneficial characteristics are both unexpected and obvious.

The compounds of Chen et al., although used for a materially different purpose than the instant application, would be obvious to try as inhibitors of SCD. This conclusion is reached because H is considered a homologue of a methyl group (as in variable R^2), and the only other difference is the point of attachment of the piperazine ring to the pyridine ring (2-position in Chen et al. and 3-position in instant formula (I)). Based on the structural similarity of the compounds of prior art and the instant application, and the fact that the compound taught by Chen et al. does have utility, claims 57, 58, 61, and 71 are rendered obvious.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 2-4, 6, 10, 11, 13-16, 18, 25, 53, 54, 56, 57, 58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4, 46, and 52 of copending Application No. 10/885901.

Determining the scope and contents of the prior art

Claim 1 of copending application 10/885901 is drawn to a method of treating a disease or condition mediated by inhibition of SCD activity in a mammal with compounds of formula (I). Compounds of formula (I) are positional isomers of compounds of formula (I) of application 10/566857. In application 10/885901, the piperazine ring is attached to the position *ortho* to the nitrogen of the pyridine ring. Examples 4 and 5 of 10/885901 (page 46 and 47 of the specification) is considered an obvious variant of compounds of formula (I) of 10/566857. In example 4, group V-R^3 is a C(O)-2-trifluoromethyl-5-fluoro-phenyl group and W-R^2 is a C(O)NH(CH_2)$_3$*i*-propyl (a (CH_2)$_3$*i*-propyl group is composed of six carbons) group. In example 5, group V-R^3 is a C(O)-2-trifluoromethyl-5-fluoro-phenyl group and W-R^2 is a C(O)NH(CH_2)$_2$*t*-butyl (a (CH_2)$_2$*t*-butyl group is composed of six carbons) group.

Ascertaining the differences between the prior art and the claims at issue

In formula (I) of application 10/566857, the piperazine ring is attached to the pyridine ring *meta* to the nitrogen atom of the pyridine ring. In formula (I) of 10/885901, the piperazine ring is attached to the *ortho* position relative to the nitrogen atom of the pyridine ring.

Resolving the level of ordinary skill in the pertinent art

One of ordinary skill in the art would recognize that formulae (I) of applications 10/566857 and 10/885901 are positional isomers of one another.

Considering objective evidence present in the application indicating obviousness or nonobviousness

In re Norris (84 USPQ 458) teaches:

Counsel for appellant in their brief acknowledge that the record herein does not establish that the admittedly new and useful compound defined by the rejected claim possesses one or more specifically identified properties to be recognized as unobvious or unexpected, as measured by every conceivable standard. Since the product claimed herein admittedly possesses no unexpected characteristics or properties, in view of what has hereinbefore been said, it is not patentable.

Sterling Drug Inc. v. Watson, Comr. Pats. (108 USPQ 37) teaches:

The test to be applied in the matter of the patentability of a compound that is a homologue of another is whether the beneficial characteristics are both unexpected and obvious.

In an instant comparison, examples 4 and 5 of 10/885901 are being used for an identical purpose to application 10/566857. A $(CH_2)_3$*i*-propyl or $(CH_2)_2$*t*-butyl group is considered a homologue of a C_7-C_8alkyl group because a C_6alkyl group only differs from a $C_{7\text{-}8}$alkyl group by a CH_2 (for a C_7alkyl group) or CH_2CH_3 (for a C_8alkyl group). Because examples 4 and 5 are considered positional isomers of formula (I) (and the same method of use is intended), claims 2-4, 6, 10, 11, 13-16, 18, 25, 53, 54, 56, 57, 58 of instant application 10/566857 are unpatentable under obvious-type double patenting with respect to application 10/885901.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

14. Claims 17, 19-23, 59-60 and 62-69 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: Chen et al. teach the closest prior art of record to in the specified claims. Claims 17 and 19-23 are not anticipated or rendered obvious because a $C(O)NH_2$ group attached to a pyridine ring is not equivalent to a $N(R^1)C(O)R^2$ group because a different type of reaction is required to couple each group to the pyridine ring. Claims 59-60 and 68-69 are not anticipated or rendered obvious because an NH_2 group is not anticipatory or obvious over a $NR^1(C_7\text{-}C_{12}$aralkyl) group. Claims 62 is not anticipated or rendered obvious because an unsubstituted phenyl ring is not anticipatory or obvious over 2-trifluoromethyl-phenyl ring. A trifluoromethyl group is electron-withdrawing, whereas a hydrogen atom is electron-donating. Claims 63-67 are not anticipated because an NH_2 group is not anticipatory or obvious over a $NR^1(C_3\text{-}C_{12}$cycloalkyl) or $NR^1(C_3\text{-}C_{12}$heterocycloalkyl) group.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624